## REMARKS

Claim 16, 46, and 47 are requested to be canceled. After this amendment, claims 1-6, 8, 10, 12-15, 17-22, 27, 28, 32-35, 37, 39, 41-45, 48, and 49 are pending in the application. All the claims stand rejected. Applicant requests that the Examiner reconsider the rejections based on the foregoing amendments and the remarks that follow.

### Claim Rejections – 35 U.S.C. § 112, Second Paragraph

In the Office Action, the Examiner rejected claim 46 under 35 U.S.C. § 112, second paragraph, "as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention." To facilitate prosecution, Applicant has canceled claim 46, obviating the rejection. Applicant, however, traverses this rejection and reserves the right to pursue canceled claim 46 in a subsequent application.

### Claim Rejections – 35 U.S.C. § 103

In the Office Action, the Examiner rejected claims 16 and 46 under 35 U.S.C. § 103 as being unpatentable over Macek *et al.* (U.S. 5,853,715) in view of Lund (U.S. 3,920,811). To facilitate prosecution of the application, Applicant has canceled claims 16 and 46, obviating the rejection. Applicant, however, traverses this rejection and reserves the right to pursue the canceled claims in a subsequent application.

In the Office Action, the Examiner rejected the remaining claims 1-6, 8, 10, 12-15, 17-22, 27, 28, 32-35, 37, 39, 41-45, 48, and 49 as being unpatentable over Macek *et al.* (U.S. 5,853,715), Studdert (U.S. 5,084,271), and Lund (U.S.

3,920,811), as further evidenced by O'Callaghan (U.S. 5,795,578), and in further view of Brown *et al.* (U.S. 4,500,513), Letchworth, III *et al.* (U.S. 5,462,734) and Kit *et al.* (U.S. 5,292,693). Applicant traverses the rejection because the Applicant respectfully contends that the Examiner has not established a proper *prima facie* case of "obviousness."

> To establish a *prima facie* case of obviousness, three basic criteria must be met. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art reference (or references when combined) must teach or suggest all the claim limitations.

MPEP § 2143 (8th ed. 2001). Applicant respectfully contends that one skilled in the art would not have a reasonable expectation that a composition, which includes a chemically inactivated **EHV-1 KyA virus**, would successfully protect a horse against diseases associated with EHV-1, EHV-4, or a combination thereof.

First, neither Macek or Studdert disclose or suggest a vaccine comprising chemically inactivated EHV-1 KyA virus or a method of administering chemically inactivated EHV-1 KyA virus. Macek discloses a "monovalent EHV-1 vaccine...comprising an EHV-1 virus represented by strain AB69." (*See* U.S. 5,853,715, column 11, claim 1, lines 26-28). The EHV-1 strain AB69 "was isolated from the infected lung tissue of an aborted fetus during a challenge study." (*See id.* at column 2, lines 17-18). Subsequently, the EHV-1 strain AB69 has been used in challenge studies. (*See id.* at column 3, line 67 to column 4, line 1.) Studdert discloses a monovalent EHV-1 vaccine and a combined vaccine based on EHV-1 and EHV-4. (*See* U.S. 5,084,271, column 8, claim 2, lines 19-22.) However, Studdert uses EHV-1 strain 438/77. (*See* '271, column 2, lines 59-60.) EHV-1 strain 438/77 was isolated from an aborted equine fetus during an outbreak in Australia in 1977.

(See Studdert, MJ., *Arch. Virol.* 77, 249-258 (1983) at page 254; and Studdert, *et al.*, *Aust. Vet. J. Vol.* 55, October, 1979, pages 488-492, at page 489.)

The EHV-1 KyA virus is attenuated and has been shown to be avirulent in young horses. (*See* Matsumura *et al.*, *Vet. Micro.* 48 (1996) 353-365). DNA analyses of the genome of EHV-1 KyA have identified deletions that remove or alter genes corresponding to ORF 1, ORF 2, gI, gE, 10k ORF, ORF 63, ORF 17, and EUS4. (*See* Colle, III *et al.*, *Virus Res.* 43(1996) 111-124, at 121). Removal of the two membrane glycoproteins gI and gE may be of particular importance in reducing the virulence of EHV-1 KyA. (*See id.*)

Macek and Studdert also disclose the unpredictable nature of attempting to use a chemically inactivated EHV-1 virus for protecting a horse against disease associated with EHV-1, EHV-4, or a combination thereof. Macek states that "a monovalent EHV-1 vaccine would not be expected to protect against EHV-1 and EHV-4 respiratory syndromes as well as from abortion caused by EHV-1." (*See* '715, column 1, lines 43-46.) Even though Macek later indicates that a monovalent EHV-1 vaccine based on the specified AB69 strain can be effective against EHV-1 and EHV-4, as noted above, Macek's claims are limited to a monovalent EHV-1 vaccine which includes this specified strain.

Studdert also fails to teach a vaccine comprising chemically inactivated EHV-1 KyA virus for protecting a horse against diseases associated with EHV-1, EHV-4, or a combination thereof. Studdert states that "[w]hether EHV-1 and EHV-4 are cross protective in horses remains unclear." (*See* '271, column 7, lines 17-18.) Further, Studdert states that "a highly specific antibody response to EHV-1, as demonstrated in the present experiments, may not cross protect against infection with EHV-4." (*See id.* at lines 37-38.) Studdert continues, "[t]he specificity of the antibody response

raises questions about the use of vaccines based on EHV-1 alone to control both EHV-1 and EHV-4 infections....[I]t seems more likely that the most appropriate vaccine for control of abortion and rhinopneumonitis should be [b]ivalent, incorporating both EHV-1 and EHV-4." (*See* '271, column 8, lines 3-5 and 12-14.) As such, based on the disclosures of Macek and Studdert, one skilled in the art would not have a reasonable expectation that a chemically inactivated EHV-1 KyA virus would successfully function as a vaccine for protecting a horse against diseases associated with EHV-1, EHV-4, or a combination thereof.

Applicant notes that the Office Action states that "[t]he inactivated equine abortion virus of Studdert is equine herpesvirus type 1, strain KyA, see column 14, lines 56-57 of O'Callaghan." (*See* Office Action, page 5, lines 15-16.) However, Applicant respectfully notes that although EHV-1 (*i.e.*, EHV subtype 1) was previously referred to as equine abortion virus (EAV) by some researchers, the "EAV" designation corresponds to the EHV-1 **subtype**, (in contrast to the EHV-4 subtype), and not the specific EHV-1 **strain**. As such, where O'Callaghan states "[t]he Kentucky A strain of equine herpes virus type 1, formerly known as equine abortion virus (EAV)," (see '578, column 14, lines 56-57), O'Callaghan means that equine herpes virus subtype 1 was formerly known as EAV, not that EHV-1 strain KyA was formerly known as EAV. The term "EHV-1" is used generically to refer to all of the EHV-1 strains. As such, neither Macek nor Studdert specifically disclose or suggest the use of a chemically inactivated KyA virus.

None of the remaining references disclose or suggest a vaccine comprising chemically inactivated EHV-1 KyA virus for protecting a horse against diseases associated with EHV-1, EHV-4, or a combination thereof. While O'Callaghan discloses a vaccine based on a recombinantly produced gD polypeptide derived from EHV-1 KyA

virus and Kit discloses EHV-1 KyA thymidine kinase mutants, neither O'Callaghan or Kit disclose or suggest a vaccine comprising a chemically inactivated EHV-1 KyA virus for protecting a horse against diseases associated with EHV-1, EHV-4, or a combination thereof. The remaining references, (*i.e.*, Lund, Brown, and Letchworth), do not disclose or suggest a chemically inactivated EHV-1 KyA virus at all. As such, Applicant respectfully contends that a *prima facie* case of unpatentability is not established by the cited references, and Applicant respectfully requests reconsideration of the rejection under 35 U.S.C. § 103.

Applicant believes that the present application is now in condition for allowance. Favorable reconsideration of the application is respectfully requested. The Examiner is invited to contact the undersigned by telephone if it is felt that a telephone interview would advance the prosecution of the present application.

Respectfully submitted,

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